CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (Proposition 65)

CHEMICALS UNDER CONSIDERATION FOR POSSIBLE LISTING VIA ADMINISTRATIVE MECHANISMS: REQUEST FOR RELEVANT INFORMATION August 22, 1997

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act) requires the Governor to publish, and update at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity.

The Act provides two mechanisms for administratively listing chemicals as known to the State to cause cancer or reproductive toxicity [Health and Safety Code Section 25249.8(b)]. One mechanism by which a chemical is listed is if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The following have been identified as authoritative bodies for purposes of the Act: the United States Environmental Protection Agency (EPA), the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the United States Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH). The criteria for listing chemicals through the "authoritative bodies" mechanism are set forth in Title 22, California Code of Regulations (22 CCR) Section 12306.

The second mechanism for the administrative listing of a chemical applies if a state or federal agency has formally required that the chemical be labeled or identified as causing cancer or reproductive toxicity. The criteria for listing chemicals through this mechanism are set forth in 22 CCR Section 12902.

As the lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency is investigating the possible listing of the chemicals identified below, based upon information in the references cited. Documentation summarizing the rationale for considering the evaluation of these chemicals for possible administrative listing is available from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the Internet at the following address: http://www.calepa.cahwnet.gov/oehha/.

OEHHA is committed to public participation and external scientific peer review in its implementation of Proposition 65, and welcomes public input on this listing process. As part of its efforts to ensure that regulatory decisions are based upon a thorough consideration of all relevant information, OEHHA is soliciting information which may be relevant to the evaluation of these chemicals in the context of the Proposition 65 administrative listing regulatory criteria (22 CCR Section 12306 or Section 12902, as appropriate).

A public forum will be held on **Wednesday, October 1, 1997** to provide an opportunity for interested parties to present oral comments and to discuss the scientific data and other information relevant to a determination as to whether these chemicals meet the criteria for listing set forth in 22 CCR Section 12306 or Section 12902. The public forum will be conducted at 10:00 a.m. in the Auditorium at 714 P Street, Sacramento, California, and will last until all business has been conducted or until 5:00 p.m.

Written comments, along with supporting information, may also be submitted to:

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301 Capitol Mall, 2nd Floor
Sacramento, California 95814
FAX: (916) 327-1097

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In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if hand-delivered or sent by fax) by October 21, 1997.

Following the review of all comments received, OEHHA will announce its intention to proceed with the listing of those candidate chemicals that meet the regulatory criteria for administrative listing in a *Notice of Intent to List Chemicals*.

A. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as carcinogens via the "authoritative bodies" mechanism:

Chemical	CAS No.	Reference
Aniline hydrochloride	142-04-1	US EPA (1989b)
C.I. Solvent Yellow 14	842-07-9	NTP (1982a)
Carbon black (by inhalation)	1333-86-4	IARC (1996)
<i>p</i> -Chloroaniline hydrochloride	20265-96-7	NTP (1989a)
<i>p</i> -Chloro- <i>o</i> -toluidine and its strong acid salts	95-69-2	IARC (1990)
Cytembena	21739-91-3	NTP (1981)
3,3'-Dichlorobenzidine dihydrochloride	612-83-9	NTP (1994)

A. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as **carcinogens** via the "authoritative bodies" mechanism (continued):

Chemical	CAS No.	Reference
	125 12 0	110 FP (100 f)
Metham sodium ¹	137-42-8	US EPA (1995a)
Methyl carbamate	598-55-0	NTP (1987)
Nalidixic acid	389-08-2	NTP (1989b)
o-Nitrotoluene	88-72-2	NTP (1996)
o-Phenylenediamine and its salts	95-54-5	US EPA (1985)
Salicylazosulfapyridine	599-79-1	NTP (1997)

B. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as **reproductive toxicants** via the "authoritative bodies" mechanism:

Chemical	CAS No.	Reference
Acrylamide	79-06-1	NIOSH (1991, 1992) NTP (1993a)
Benzo[a]pyrene	50-32-8	IARC (1983)
Boric Acid ^{1,2} 1,3-Butadiene	10043-35-3 106-99-0	US EPA (1993a, b) NIOSH (1984) US EPA (1989a) NTP (1993b)
Carbon dioxide (by inhalation) ^{1,2}	124-38-9	US EPA (1991a, b)
o,p'-DDT	789-02-6	IARC (1991) NIOSH (1988) US EPA (1988a)
p,p'-DDT	50-29-3	IARC (1991) NIOSH (1988) US EPA (1988a)
DDT, technical grade		IARC (1991) NIOSH (1988) US EPA (1988a)
(2,4-dichlorphenoxy) acetic acid	94-75-7	US EPA (1988c)
2,4-D n-butyl ester	94-80-4	US EPA (1988c)
2,4-D isopropyl ester	94-11-1	US EPA (1988c)
2,4-D isooctyl ester	25168-26-7	US EPA (1988c)
Propylene gylcol butyl ether ester (of 2,4-D)	1928-45-6	US EPA (1988c)
2,4-D butoxyethanol ester	1929-73-3	US EPA (1988c)

B. Chemicals which may meet the criteria set forth in 22 CCR Section 12306 for listing as **reproductive toxicants** via the "authoritative bodies" mechanism (continued):

Chemical	CAS No.	Reference
2,4-D dimethylamine salt	2008-39-1	US EPA (1988c)
2,4-D butyric acid ¹ Endrin	94-82-6 72-20-8	US EPA (1988c, 1994a, b) US EPA (1980, 1992b)
Ethylene dibromide	106-93-4	NIOSH (1977) US EPA (1987a, b)
Linuron ¹ Metham Sodium ¹	330-55-2 137-42-8	US EPA (1994a, b) US EPA (1994a, b)
Oxadiazon ¹	19666-30-9	US EPA (1994a, b)
Tetraborate and its salts (including Sodium Borate) ^{1,2}		US EPA (1993a, b)
Vinclozolin ¹ Zearalenone	50471-44-8 17924-92-4	US EPA (1988b, 1994a, b) NTP (1982b) IARC (1993)

¹On July 21, 1997 and August 4, 1997, letters were sent to the U.S. Environmental Protection Agency seeking clarification on its determination that the chemical had been identified as causing reproductive toxicity (see attached letters).

²On August 4, 1997, a letter was sent to the US Food and Drug Administration seeking clarification on its determination that the chemical had been identified as causing reproductive toxicity (see attached letter).

C. Chemicals which may meet the criteria set forth in 22 CCR Section 12902 for listing as **reproductive toxicants** via the "formally required to be labeled or identified" mechanism:

Chemical	CAS No.	Reference
Amoxapine	14028-44-5	FDA (1988a)
Beclomethasone dipropionate	5534-09-8	FDA (1988b)
Clobetasol propionate	25122-46-7	FDA (1995a)
Codeine phosphate	52-28-8	FDA (1989)

C. Chemicals which may meet the criteria set forth in 22 CCR Section 12902 for listing as reproductive toxicants via the "formally required to be labeled or identified" mechanism (continued):

Chemical	CAS No.	Reference
Flunisolide	3385-03-3	FDA (1984)
Fluticasone propionate	80474-14-2	FDA (1995b)
Histrelin acetate		FDA (1991)
Levonorgestrel implants	797-63-7	FDA (1995c)
Pravastatin sodium	81131-70-6	FDA (1996)

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